

Food and Drug Administration, HHS

§ 1304.02

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AUTHORITY: 21 U.S.C. 821, 827, 871(b), 958(d), 965, unless otherwise noted.

GENERAL INFORMATION

§ 1304.01 Scope of Part 1304.

Inventory and other records and reports required under section 307 or section 1008(d) of the Act (21 U.S.C. 827 and 958(d)) shall be in accordance with, and contain the information required by, those sections and by the sections of this part.

[36 FR 7789, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1304.02 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term *Act* means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Sub-

stances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

(b) The term *commercial container* means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term *commercial container* does not include any package liner, package insert of other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(c) The term *dispenser* means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

(d) The term *individual practitioner* means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(e) The term *institutional practitioner* means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(f) The term *mid-level practitioner* means an individual practitioner (as defined in § 1304.02(d)), other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the state in which they practice.